



LAW OFFICES OF  
SYNNESTVEDT & LECHNER LLP  
2600 ARAMARK TOWER  
1101 MARKET STREET  
PHILADELPHIA, PA 19107-2950  
TELEPHONE (215) 923-4466  
FACSIMILE (215) 923-2189  
E-MAIL [synnlech@synnlech.com](mailto:synnlech@synnlech.com)  
[www.synnlech.com](http://www.synnlech.com)

October 2, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re/ Application of Z. Saidi and B. Klyashchitsky

Application No. 10/019,100

Filed December 20, 2001

Examiner: Not Yet Assigned

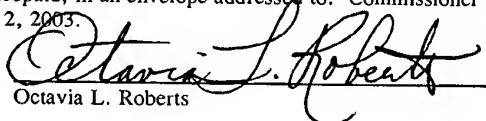
Group Art Unit: Not Yet Assigned

AQUEOUS COMPOSITIONS CONTAINING CORTICOSTEROIDS  
FOR NASAL AND PULMONARY DELIVERY

(Attorney Docket No. P24,800-A USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence, along with any other papers indicated as being enclosed, is being deposited with the United States Postal Services, as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on October 2, 2003.

  
Octavia L. Roberts

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(B)

Sir:

It is requested respectfully that the information identified on the enclosed Form PTO-1449 (Modified) be made of record and considered with respect to the above-referenced patent application. The Examiner is requested to indicate that each item on the enclosed Form PTO-1449 (Modified) has been considered by initialing and dating the enclosed Form and returning a copy of same to the undersigned.

Group Art Unit: Not Assigned Yet  
Application No. 10/019,100

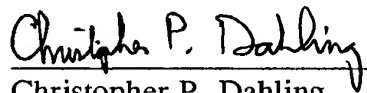
October 2, 2003  
Docket No. P24,800-A USA

This Information Disclosure Statement is filed before a first Office Action on the merits. The above-referenced patent application is a Continuation-in-Part of U.S. Patent Application Serial No. 09/105,838 filed June 26, 1998, now U.S. Patent No. 6,241,969. The publications listed on the Form PTO-1449 were cited by or submitted to the Patent Office during the pendency of the parent application. Copies of such publications are not provided as permitted by 37 C.F.R. §1.98(d).

Identification of information on the attached Form, or in this statement, is not an admission that such information is prior art to the invention claimed in the present application or that such information is in an analogous art area.

The Commissioner is authorized hereby to charge any fees or credit any overpayment associated with this Statement (copy enclosed) to Deposit Account Number 19-5425.

Respectfully submitted,

  
\_\_\_\_\_  
Christopher P. Dahling  
Registration No. 51,140

Synnestvedt & Lechner LLP  
2600 Aramark Tower  
1101 Market Street  
Philadelphia, PA 19107  
Telephone (215) 923-4466  
Facsimile (215) 923-2189

FORM PTO-1449 (MODIFIED)

ATTORNEY DOCKET NO.  
P24,800-A USAAPPLICATION NO.  
10/019,100LIST OF PATENTS AND OTHER  
PUBLICATIONS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT  
(USE SEVERAL SHEETS IF NECESSARY)

## APPLICANT

Z. Saidi and B. Klyashchitsky

## FILING DATE

December 20, 2001

## GROUP ART UNIT

NYA

U.S. Department of Commerce  
Patent and Trademark Office

## U.S. PATENT DOCUMENTS


| EXAMINER INITIALS |    | DOCUMENT NO. | DATE       | NAME                 | CLASS | SUB-CLASS | FILING DATE |
|-------------------|----|--------------|------------|----------------------|-------|-----------|-------------|
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|                   | AB | 4,567,161    | 01/28/1986 | Posanski et al.      | 514   | 23        | 06/28/1983  |
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## FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS |    | DOCUMENT NO. | DATE       | COUNTRY |
|-------------------|----|--------------|------------|---------|
| /L.S./            | BA | 2083927      | 12/11/1993 | CA      |

## OTHER PUBLICATIONS

|        |    |  |
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| /L.S./ | CA | Bochner et al., "Immunological Aspects of Allergic Asthma," <u>Annu. Rev. Immunol.</u> , <u>12</u> , 295-335 (1994)  |
|        | CB | Brain, et al., "Aerosols: Basics and Clinical Considerations," <u>Bronchial Asthma</u> , Second Edition, Weiss, E.B. et al., (eds.), Little, Brown and Company, 594-603 (1985)   |
|        | CC | Eastman Chemical Company, "Eastman Vitamin E TPGS: Properties and Applications," <u>Pharmaceutical Ingredients</u> , 1-21 (Oct. 1996)  |
|        | CD | Goodman & Gilman's, "The Pharmacological Basis of Therapeutics," Ninth Edition, McGraw-Hill, 662-664, 666-667, 1470-1471, 1473, 1480 (1996)  |
|        | CE | Klyashchitsky et al., "Drug Delivery Systems for Cyclosporine: Achievements and Complications," <u>J. Drug Targeting</u> , <u>5(6)</u> , 443-458 (1998)  |
|        | CF | Klyashchitsky et al., "Nebulizer-Compatible Liquid Formulations for Aerosol Pulmonary Delivery of Hydrophobic Drugs: Glucocorticoids and Cyclosporine," <u>J. Drug Targeting</u> , <u>7(2)</u> , 79-99 (1999)  |
|        | CG | Ly et al., "Evaluation and Application of Hydrophilic Tocopherol Polyethylene Glycol Derivatives as Enhancers of Drug Solubility," College of Pharmacy and Allied Health Professions, St. John's University, Jamaica, NY, Presentation ID: 3419, Nov. 5, 1997, 1 page summary. |
|        | CH | Ly, et al., "Evaluation of (+)- $\alpha$ -Tocopherol Polyethylene Glycol 1000 (TPG) as an Enhancer of Drug Solubility in Aqueous Solution," <u>Proc. 2<sup>nd</sup> World Meeting APGI/APV</u> , Paris, May 25/28, 1-2 (1998)  |



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| CI | Pavord et al., "Pharmacokinetic Optimization of Inhaled Steroid Therapy in Asthma," <u>Clin. Pharmacokinet.</u> , <u>25</u> (2), 126-135 (1993)                        |
| CJ | Schreier et al., "Pulmonary Delivery of Liposomes," <u>J. Control. Release</u> , <u>24</u> , 209-223 (1993)  |
| CK | Waldrep, et al., "High dose Cyclosporin A and Budesonide-liposome aerosols," <u>Intl. J. Pharm.</u> , <u>152</u> (1), 27-36 (1997)                                     |
| CL | Waldrep, et al., "Nebulized Glucocorticoids in Liposomes: Aerosol Characteristics and Human Dose Estimates," <u>J. Aerosol Medicine</u> , <u>7</u> (2), 135-145 (1994) |

EXAMINER

DATE CONSIDERED

/Layla Soroush/

04/26/2010

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformation *and* not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 2

October 2, 2003